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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,194	07/18/2003	Jeffrey H. Baxter	6815.US.D1	2664

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EXAMINER
GHALI, ISIS A D

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
05/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,194	BAXTER, JEFFREY H.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/19/2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,9 and 11-37* is/are pending in the application.

4a) Of the above claim(s) *21-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,9 and 11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 02/19/2007.

Election/Restrictions

1. This application contains claims 21-37 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 4, 7, 8 and 10 have been canceled.

Claims 1-3, 5, 6, 9, 11-20 are included in the prosecution.

The following rejections have been overcome by overcome by virtue of virtue of applicant's amendment and remarks:

(A) The rejection of claims 2-20 under 35 U.S.C. 112, second paragraph, as being indefinite.

(B) The rejection of claims 1-20 on the ground of nonstatutory obviousness-type double patenting over claims 1-21 of commonly assigned U.S. Patent No. 6,906,038 ('038) in view of any of JP 55-105652 ('652), JP 58-018320 ('320) or US 3,178,342

('342); and further in view of US 6,572,898 ('898), US 5,489,440 ('440) and US 5,733,579 ('579).

The following objection has been discussed in the previous office action, and is maintained for reasons of record:

Specification

2. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Applicant did not indicate that the specification has been checked for possible errors, therefore, the objection is maintained.

The following new ground of rejections are necessitated by applicant's amendment:

The claims as currently amended recite that ingredient (e) of the claimed solution requires source of glutamine selected from **EITHER** N-acetyl-L-glutamine **OR** nutritionally equivalent salts thereof. Claim 1 as currently amended does not require glutamine and its salts. EP '462 teaches N-acetyl-L-glutamine, therefore, JP '652, JP '320 and US '342 that relied upon for reciting specific salts of N-acetyl-L-glutamine are no longer necessary to form the obviousness rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-3, 5, 6, 9, 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 540 462 ('462) in view of US 6,572,898 ('898).

EP '462 teaches liquid nutritional solution comprising N-acetyl-L-glutamine salts (abstract; page 2, lines 42-44, 55-58; page 3, lines 57-58). The amount of glutamine given ranges from 0.1 to 70 g/kg/ day (page 3, lines 9-15), and these amounts are calculated to be equal to 0.532 to 37.24 mmol/kg/day, i.e. applicant's claimed amounts fall within the disclosure of the reference. When glutamine added to drink, it does not inhibit gastric emptying to a physiological significant degree, and accordingly secures maximum fluid and nutrient availability (page 2, lines 49-50). EP '462 teaches that the liquid formulation further comprises carbohydrate such as dextrose and fructose, and electrolytes including sodium, potassium and chloride (page 3, lines 23-26, 40-54; page 4, lines 7-26). The composition comprises flavoring agent and the like (page 2, line 58).

However, EP '462 does not teach the amounts of sodium, potassium and chloride and their salts as instantly claimed, citrate in the solution and its amount, and

gelling agents as claimed in claim 18. EP '462 does not teach sweetener as claimed in claim 17.

US '898 teaches convenient, non-threatening, and easy to administer rehydration composition comprising electrolyte and gelling agents to be consumed by children and elderly who cannot tolerate liquid or frozen forms of electrolyte (abstract; col.5, lines 1-3). The composition comprises from 20-60 mEq of sodium per liter, 15-25 mEq of potassium per liter, 25-50 mEq of chloride per liter, and 20-50 mEq of citrate per liter (col.3, lines 115-26). The carbohydrate included fructose and dextrose and is present in an amount of 2.473 wt % (col.6, lines 28-30; col.9, example 1). The gelling agent includes carrageenan, agar, alginate, or gums (col.5, line 61-col.6, line 9). The composition further comprises flavoring agent and sweeteners (col.6, lines 41-43).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide solution comprising solution comprising N-acetyl-L-glutamine salts, carbohydrate sodium, potassium and chloride as disclosed by EP '462, and further add gelling agent and citrate, and adjust the amount to the amounts disclosed by US '898, motivated by the teaching of US '898 that the disclosed composition comprising citrate and other electrolytes in the disclosed amounts help rehydration treatment, and gelling agents provides a convenient, non-threatening, and easy to administer composition that can be consumed by children and elderly who cannot tolerate liquid or frozen formulations, with reasonable expectation of having composition comprising N-acetyl-L-glutamine salts, carbohydrate sodium, potassium, chloride, and citrate in the claimed amounts, and further comprising gelling agent that

makes the composition more tolerable by children and elderly, convenient, non-threatening, and easy to administer.

Response to Arguments

5. Applicant's arguments filed 02/19/2007 have been fully considered but they are not persuasive. Applicant traverses this rejection by arguing that EP '462 teaches L-glutamine to prevent reduced glutamine in blood during exercise. Applicant argues that EP '462 teaches many different glutamine derivatives including N-acetyl-L-glutamine, but only exemplifies L-alanyl-L-glutamine and fails to disclose formulation that actually contains N-acetyl-L-glutamine. Applicants argue that they have shown that N-acetyl-L-glutamine is more effective than free glutamine and peptide form of glutamine on celiac disease. Applicant argues that the comparison done on N-acetyl-L-glutamine versus free glutamine in the present example 4 showed less marked deleterious effect of antioxidant on animal consumed N-acetyl-L-glutamine than on animal consumed glutamine. Applicants argue that N-acetyl-L-glutamine has more effect than orally administered glutamine and the presently claimed composition is not obvious over the EP '462.

In response to this argument, applicant's attention is directed to the scope of the present claims that are directed to composition and all the elements of the composition are taught by the combined teaching of the reference, and the future intended use of the composition does not impart patentability to the claims.

Regarding the argument that the reference does not exemplify composition comprising N-acetyl-L- glutamine, it is argued that in considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). The disclosed examples and preferred embodiment do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

Regarding the comparison done by the present example 4, the comparison does not commensurate in scope with the claims because it is not comparing the claimed composition with otherwise, however, it compares the effect of N-acetyl-L-glutamine versus free glutamine. No side-by-side comparison of the present claimed composition with the prior art composition. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by

their specific disclosure. In re Bozek, 163 USPQ 545 (CCPA 1969). In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP '462 in view of US '898 and further in view of US '440.

The teachings of EP '462 combined with US '898 are discussed above.

However, the combined teaching of EP '462 and US '898 does not teach rice flour in the composition as claimed by claim 19.

US '440 teaches oral rehydration solution comprising rice flour that resulted in lower net fluid intake and reduced stool output during rehydration period of treatment (abstract; col.3, lines 51-55)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an aqueous solution containing sodium, potassium, citrate, chloride, carbohydrate, and of N-acetyl-L-glutamine as disclosed by the combined teaching of EP '462 and US '898, and further add rice flour to the composition as disclosed by US '440, motivated by the teaching of US '440 that rice flour results in lower net fluid intake and reduced stool output during rehydration period of treatment, with reasonable expectation of having an aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate, salt of N-acetyl-L-glutamine, and rice flour that treats hydration effectively.

Response to Arguments

7. Applicant's arguments filed 02/19/2007 have been fully considered but they are not persuasive. Applicant hereby repeats the arguments as in section 5 of this office action. Therefore, the examiner repeats the response as above.

8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP '462 in view of US '898 and further in view US '579.

The teachings of EP '462 combined with US '898 are discussed above. However, the combined teaching of EP '462 and US '898 does not teach indigestible oligosaccharides as claimed in claim 20.

US '579 teaches oral rehydration solution comprises indigestible oligosaccharide that shown to have beneficial impact on microbial flora of the intestine, reduces serum cholesterol, and also alleviates constipation (abstract; col.5, line 64-col.6, line 12).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an aqueous solution containing sodium, potassium, citrate, chloride, carbohydrate, and of N-acetyl-L-glutamine as disclosed by the combined teaching of EP '462 and US '898, and further add indigestible oligosaccharide as disclosed by US '579, motivated by the teaching of US '579 that indigestible oligosaccharide shown to have beneficial impact on microbial flora of the intestine, reduces serum cholesterol, and also alleviates constipation, with reasonable expectation of having an aqueous solution comprising sodium, potassium, citrate,

chloride, carbohydrate, salt of N-acetyl-L-glutamine, and indigestible oligosaccharide, wherein the composition treats hydration without altering the intestinal flora, and further reduces serum cholesterol.

Response to Arguments

9. Applicant's arguments filed 02/19/2007 have been fully considered but they are not persuasive. Applicant hereby repeats the arguments as in section 5 of this office action. Therefore, the examiner repeats the response as above.

10. Claims 1-3, 5, 6, 9, 11-20 are rejected under 35 U.S.C. 103(a) as being obvious over US 6,906,038 ('038) in view of EP 0 540 462 ('462), and further in view of US '898 as applied to claim 18.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the

application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

US '038 teaches an aqueous solution containing 30-95 mEq of sodium ions, 10-30 mEq of potassium ions, 10-40 mEq of citrate, 30-80 mEq of chloride, less than 3% of carbohydrate such as fructose and dextrose, glutamine derivatives, gelling agent, rice flour, and indigestible oligosaccharide, and further comprising flavor and sweetener (abstract; col.4, lines 12-67; col.5, lines 1-20, 36-40, 57060; col.6, lines 21, claims 1-21).

However, US '038 does not explicitly teach N-acetyl-L-glutamine or its salts as instantly claimed in claim 1, or the specific gelling agents as instantly claimed in claim 18.

EP '462 teaches liquid nutritional solution comprising N-acetyl-L-glutamine salts (abstract; page 2, lines 42-44, 55-58; page 3, lines 57-58). The amount of glutamine given ranges from 0.1 to 70 g/kg/ day (page 3, lines 9-15), and these amounts are calculated to be equal to 0.532 to 37.24 mmol/kg/day, i.e. applicant's claimed amounts fall within the disclosure of the reference. When glutamine added to drink, it does not inhibit gastric emptying to a physiological significant degree, and accordingly secures maximum fluid and nutrient availability (page 2, lines 49-50). EP '462 teaches that the liquid formulation further comprises carbohydrate such as dextrose and fructose, and electrolytes including sodium, potassium and chloride (page 3, lines 23-26, 40-54; page 4, lines 7-26). The composition comprises flavoring agent and the like (page 2, line 58).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an aqueous solution containing sodium, potassium, citrate, chloride, carbohydrate and glutamine as disclosed by US '038, and replace glutamine with N-acetyl-L-glutamine as disclosed by EP '462, motivated by the teaching of EP '462 that derivatives of glutamine including N-acetyl-L-glutamine when added to drink, it does not inhibit gastric emptying to a physiological significant degree, and accordingly secures maximum fluid and nutrient availability, with reasonable expectation of having aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate and N-acetyl-L-glutamine that provides nutrients to the human being and does not inhibit gastric emptying to a physiological significant degree, and accordingly secures maximum fluid and nutrient availability.

The combined teaching of US '038 and EP '462 does not teach the specific gelling agents as claimed in claim 18.

US '898 teaches convenient, non-threatening, and easy to administer rehydration composition comprising electrolyte and gelling agent to be consumed by children and elderly who cannot tolerate liquid or frozen forms of electrolyte (abstract; col.5, lines 1-3). The gelling agent includes carrageenan, agar, alginate, or gums (col.5, line 61-col.6, line 9). The composition comprises electrolytes and carbohydrate (col.3, lines 115-26; col.6, lines 28-30; col.9, example 1).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate, N-acetyl-L-glutamine, and gelling agent as taught by US

'038 combined with EP '462, and select carrageenan, agar, alginate, or gums disclosed by US '898, motivated by the teaching of US '898 that these gelling agents provides a convenient, non-threatening, and easy to administer composition that can be consumed by children and elderly who cannot tolerate liquid or frozen forms of electrolyte, with reasonable expectation of having an aqueous solution comprising sodium, potassium, citrate, chloride, carbohydrate, salt of N-acetyl-L-glutamine, and gelling agent such as carrageenan, agar, alginate, or gums, wherein the composition is convenient, non-threatening, and easy to administer composition that can be consumed by children and elderly who cannot tolerate liquid or frozen compositions.

Response to Arguments

11. Applicant's arguments with respect to claims 1-3, 5, 6, 9, 11-20 over US 038 in view of any of JP '652, JP '320, or US '342 have been considered but are moot in view of the new ground(s) of rejection.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. JP 55-105652 teaches aluminum salts of N-acetyl-L-glutamine solution that is highly pure and industrially advantageous to treat gastric ulcer (see the provided abstract). JP 58-018320 teaches aluminum salts of N-acetyl-L-glutamine solution that is free from astringent taste and useful as anti-ulcer agent (see the provided abstract). US 3,178,342 teaches dimethyl ethanol amine salt of acetyl glutamine given orally and has remarkable effect on motor system and psychic

development of the human being without affecting the autonomous nervous system (col.1, lines 1-18, 46-50; col.2, lines 66-67; 71; col.3, lines 1-4; claims 1-3).

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

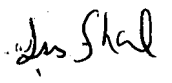
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1615

IG



ISIS GHALI
PRIMARY EXAMINER